UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MONTEFIORE MEDICAL CENTER, 111 East 210th Street Bronx, New York 10467))))	
THE NEW YORK AND PRESBYTERIAN HOSPITAL f/k/a NEW YORK – PRESBYTERIAN/ BROOKLYN METHODIST, 506 Sixth Street Brooklyn, NY 11215	Case No.)))	
NEWYORK-PRESBYTERIAN/QUEENS, 56-45 Main Street Flushing, NY 11355,))))	
Plaintiffs,)))	
v.))	
XAVIER BECERRA, Secretary, United States Department of Health and Human Services, 200 Independence Avenue S.W. Washington, District of Columbia 20201,)))))	
Defendant.	,))	
))))	

COMPLAINT FOR JUDICIAL REVIEW AND DECLARATORY AND INJUNCTIVE RELIEF UNDER THE MEDICARE ACT

NATURE OF ACTION

1. This case again presents the question of whether Defendant's agency can abruptly change its interpretation of a statute that it previously maintained was ambiguous, receive three adverse decisions from the Court of Appeals (with the latest one affirmed by the Supreme Court)

finding that the agency made and applied the change in a procedurally invalid manner, and then—two decades later—effectuate the same change retroactively as though there is a blank slate on which it is entitled to yet another do-over. The answer is no.

2. Defendant's administrative review board has certified this matter for expedited judicial review under 42 U.S.C. § 139500(f)(1) because it determined that it is without the authority to decide the legal questions presented in this case. The case arises from Defendant's attempted 2004 change in the calculation of the Medicare Part A disproportionate share hospital ("DSH") payment with respect to inpatient hospital days for patients who opted to enroll in Medicare Advantage plans under Part C of the Medicare statute. The Court of Appeals has now ruled against the agency in three actions challenging the agency's repeated attempts to accomplish the change that significantly reduces Medicare DSH payments to hospitals. See Northeast Hosp. Corp. v. Sebelius, 657 F.3d 1, 16–17 (D.C. Cir. 2011) (finding application of the 2004 rule to prior periods impermissibly retroactive); Allina Health Servs. v. Sebelius, 746 F.3d 1102, 1105 (D.C. Cir. 2014) ("Allina I") (vacating the 2004 rule because it was not a logical outgrowth of the proposed rule); Allina Health Servs. v. Price, 863 F.3d 937, 943-44 (D.C. Cir. 2017) (holding that the agency must undertake notice-and-comment rulemaking before effectuating the policy reflected in the vacated 2004 rule), aff'd sub nom. Azar v. Allina Health Servs., 587 U.S. 566 (2019) ("Allina II"). The plaintiff hospitals in the instant action were also plaintiffs in the earlier Allina litigation. See Allina I, 746 F.3d 1102; Allina II, 587 U.S. 566; Compl. ¶¶ 1–3, 31–32, Allina Health Sys. v. Burwell, No. 16-cv-150 (D.D.C. Jan. 29, 2016) ("Allina III"), ECF No. 1; Allina Health Sys. v. Becerra, No. 1:23-cv-02144 (D.D.C. July 24, 2023) ("Allina IV"), ECF No. 1. Nearly 19 years after it originally promulgated the 2004 final rule vacated in Allina I, the agency in 2023 issued a final rule seeking to readopt retroactively the change from the still-vacated 2004

rule previously readopted prospectively in 2013. Now, a full two decades later, the plaintiff hospitals once again seek, and the law demands, an end to the agency's unlawful actions.

3. The 2023 rule attempting to readopt the same 2004 change for periods even prior to 2004 should be rejected because it disregards Allina I, Northeast Hospital, and Allina II, is otherwise contrary to law, exceeds the agency's retroactive rulemaking authority under the Medicare statute, and is arbitrary and capricious for failing any test of reasoned decision-making. Among other infirmities, this final action misconstrues the legal effect of the vacatur of the 2004 rule in Allina I, 746 F.3d at 1105, which restored the pre-2004 DSH Part C standard. By excluding Part C days from the numerator of the Medicaid fraction for any patients discharged prior to October 1, 2004, and by disclaiming any pre-2004 policy or practice treating Part C days as not Part-A-entitled days, the agency also again disregards Northeast Hospital. 657 F.3d at 16–17. In addition, the rule violates 42 U.S.C. § 1395hh(e) because neither of the narrow exceptions for retroactive rulemaking applies here given that (1) the ambiguous DSH statute does not require any specific treatment of Part C days in the DSH calculation, see Allina I, 746 F.3d at 1106; Northeast Hosp., 657 F.3d at 13, and the DSH statute does not require a retroactive rule for the agency to comply with its obligation to make payments; and (2) the 2023 rule cannot be said to be in the public interest, given that it offends fundamental notions of justice, disregards the significant public interest in advance notice-and-comment rulemaking, and results in thousands of safety-net hospitals losing billions of dollars in funding that has been illegally withheld for years. Nor can the agency retroactively "establish," rather than "change," the Part C DSH standard under the plain language of the Medicare statute. See 42 U.S.C. § 1395hh(e)(1)(A). And even if there were any ambiguity as to whether the agency had the authority to engage in this retroactive rulemaking under section 1395hh(e) (and the agency clearly lacks that authority), any such ambiguity would

need to be read against retroactivity, given the well-established presumption in law against retroactivity. The rule conflicts with other provisions of the Medicare statute prohibiting action against providers with respect to noncompliance with its substantive change and precluding untimely reopening and revisions of claims payment determinations. *See* 42 U.S.C. §§ 1395hh(e)(1)(C), 1395gg(c).

- 4. In addition, the final action violates *Allina II* and is procedurally invalid under 42 U.S.C. § 1395hh(a)(4), which bars the agency from effectuating or applying the same policy change from the rule vacated in *Allina I* as a logical outgrowth failure, 746 F.3d at 1105, at least until *after* the effective date of a legally sound notice-and-comment process adopting the rule prospectively only, *see Allina II*, 863 F.3d at 945; *Allina II*, 587 U.S. at 581–84. The rule further violates *Allina II* and is procedurally invalid under 42 U.S.C. § 1395hh(a)(2) because the agency again seeks to make the change "take effect" *before* affording impacted providers the requisite notice and comment. *See* 42 U.S.C. § 1395hh(a)(2); *Allina II*, 587 U.S. at 571–80.
- 5. The final rule is also arbitrary and capricious for many reasons, including that the agency failed (1) to acknowledge, let alone explain, that the policy readopted retroactively in the rule departed from the pre-2004 rule and practice previously readopted prospectively in 2013; (2) to consider properly the hospitals' reliance interests in changing its pre-2004 position; and (3) to recognize the enormous adverse financial impact on hospitals of its policy change, despite asserting that it had already made hospitals' DSH payments based on the change and having represented to the Supreme Court in seeking certiorari that the impact with respect to only one of the DSH fractions was "between \$3 and \$4 billion for federal fiscal years ("FFY") 2005 through 2013." Once again, through the 2023 rule, the agency continues to deny a 2004 change in policy and practice and made one last-ditch effort to accomplish the same change in yet another

substantively and procedurally improper fashion. It must be set aside to stop the agency's repeated circumvention of the law.

JURISDICTION AND VENUE

- 6. This action arises under the Medicare Act, Title XVII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*
 - 7. Jurisdiction is proper under 42 U.S.C. § 139500(f)(1).
 - 8. Venue is proper in this judicial district under 42 U.S.C. § 139500(f)(1).

PARTIES

- 9. The plaintiff hospitals in this action are:
- a. Montefiore Medical Center, Provider No. 33-0059 ("Montefiore"), for its cost reporting periods ending December 31, 2005, December 31, 2007, and December 31, 2008;
- b. The New York and Presbyterian Hospital f/k/a New York Presbyterian/Brooklyn Methodist, Provider No. 33-0236 ("New York Methodist"), for its cost reporting periods ending December 31, 2009, and December 31, 2010; and
- c. NewYork-Presbyterian/Queens, Provider No. 33-0055 ("New York Queens"), for its cost reporting periods ending December 31, 2011, and December 31, 2012.
- 10. The Defendant is Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services ("Secretary"), the federal agency that administers the Medicare program. References to the Secretary herein are meant to refer to him, to his subordinates, and to his official predecessors or successors, as the context requires.
- 11. The Centers for Medicare & Medicaid Services ("CMS") is the component of the Secretary's agency with responsibility for day-to-day operation and administration of the Medicare program. CMS was formerly known as the Health Care Financing Administration. References to CMS herein are meant to refer to the agency and its predecessors.

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LEGAL AND REGULATORY BACKGROUND

Medicare DSH Payment

- 12. Part A of the Medicare Act covers "inpatient hospital services." 42 U.S.C. § 1395d(a)(1). Since 1983, the Medicare program has paid most hospitals for the operating costs of inpatient hospital services under the prospective payment system ("PPS"). 42 U.S.C. § 1395ww(d); 42 C.F.R. Part 412. Under PPS, Medicare pays predetermined, standardized amounts per discharge, subject to certain payment adjustments. *Id.* One of the PPS payment adjustments is the DSH payment. *See* 42 U.S.C. § 1395ww(d)(5)(F); 42 C.F.R. § 412.106.
- 13. A hospital that serves a disproportionate share of low-income patients is entitled to an upward percentage adjustment to the standard PPS rates per discharge. *See* 42 U.S.C. § 1395ww(d)(5)(F); *see also* 42 C.F.R. § 412.106. A hospital may qualify for a DSH adjustment based on its "disproportionate patient percentage." 42 U.S.C. §§ 1395ww(d)(5)(F)(i)(I) and (d)(5)(F)(v); 42 C.F.R. § 412.106(c)(1). The disproportionate patient percentage determines both a hospital's qualification for the DSH payment and the amount of the payment. *See* 42 U.S.C. §§ 1395ww(d)(5)(F)(iv) and (vii)–(xiii); 42 C.F.R. § 412.106(d). The disproportionate patient percentage is defined as the sum of two fractions expressed as percentages. 42 U.S.C. § 1395ww(d)(5)(F)(vi).
- 14. The first fraction that is used to compute the DSH payment is commonly known as the "Medicaid fraction." The statute defines the Medicaid fraction as:

[T]he fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under [the Medicaid statute, title XIX of the Social Security Act], but who were *not entitled to benefits under part A* of [the Medicare statute, title XVIII of the Social Security Act], and the denominator of which is the total number of the hospital's patient days for such period.

42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) (emphasis added). As reflected in the italicized language above, the numerator of the Medicaid fraction consists of days for patients who were both eligible for medical assistance under the Medicaid statute and "not entitled to benefits under part A" of the Medicare statute.

15. The other fraction that is used to compute the DSH payment is the "Medicare part A/SSI fraction" or "SSI fraction." The statute defines this fraction as:

[T]he fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were *entitled to benefits under part A* of [the Medicare statute] and were entitled to supplemental security income benefits (excluding any State supplementation)... and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were *entitled to benefits under part A* of [the Medicare statute.]

42 U.S.C. § 1395ww(d)(5)(F)(vi)(I) (emphases added). As the italicized language indicates, the Medicare Part A/SSI fraction consists solely of days for patients who were "entitled to benefits under part A" of Medicare. The denominator includes all Medicare Part A days, whereas the numerator includes only those Part A days for patients who are also entitled to social security income ("SSI") benefits under title XVI of the Social Security Act. The Medicare Part A/SSI fraction is computed for each FFY by the agency and must be used to compute a hospital's DSH payment for the cost reporting period beginning in the federal fiscal year. 42 C.F.R. §§ 412.106(b)(2)–(3). A hospital may elect to have the Medicare Part A/SSI fraction recalculated based on patient days in its own cost reporting period instead of the federal fiscal year. See id.; see also 42 U.S.C. § 1395ww(d)(5)(F)(vi), (vi)(I) (requiring calculation of Medicare Part A/SSI fraction based on the cost reporting period); 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (stating that while the agency would rely on the federal fiscal year, it was "affording all hospitals the option to determine their number of patient days of those dually entitled to Medicare Part A and SSI for their own cost reporting periods").

- 16. After the close of each fiscal year, a hospital is required to file a "cost report" with a Medicare Administrative Contractor designated by the agency. 42 C.F.R. §§ 413.20(b), 413.24. The cost report includes claims for DSH payments for the period. *See* Medicare Claims Processing Manual, CMS Pub. 100-04, ch. 3, § 20.3, https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf ("[T]he [contractor] will identify hospitals that are eligible to receive the DSH adjustment and make interim payments subject to a year-end settlement based upon the hospital's DSH percentage for the cost reporting period.").
- 17. The Medicare Administrative Contractor analyzes a hospital's cost report and issues a year-end payment determination, called a Notice of Program Reimbursement ("NPR"), as to the amount of Medicare program reimbursement due to the hospital for services furnished to Medicare patients during the fiscal year covered by the cost report. *See* 42 C.F.R. § 405.1803; *In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d 89, 92 (D.D.C. 2004), *aff'd*, 414 F.3d 7 (D.C. Cir. 2005).
- 18. The Medicare Administrative Contractor also makes estimated payments to hospitals on an interim basis as claims are paid throughout a cost reporting period, including DSH payments. See Medicare Claims Processing Manual, ch. 3, § 20.3; 42 C.F.R. § 413.64(f)(2); Medicare Fin. Mgmt. Manual, **CMS** Pub. 100-06, ch. 8, § 10.5, http://www.cms.gov/manuals/downloads/Fin106c08.pdf.
- 19. A hospital may appeal a Medicare Administrative Contractor's determination as to the total amount of Medicare program reimbursement due the hospital for the fiscal year covered by a cost report to the agency's Provider Reimbursement Review Board ("Board"). *See* 42 U.S.C. § 1395oo(a)(1)(A); 42 C.F.R. §§ 405.1835–405.1877.

20. A hospital has the right to a hearing before the Board if it is dissatisfied with the contractor's payment determination in an NPR as to the total amount of program reimbursement due to the hospital for its cost reporting period. 42 U.S.C. § 1395oo(a)(1); see also 42 C.F.R. §§ 405.1835; 405.1837. The statute further requires a minimum amount in controversy and that the appeal be filed timely. 42 U.S.C. § 1395oo(a)(2)–(3).

Expedited Judicial Review

21. The Medicare statute authorizes the Board to determine that it is without authority to decide a question of law or regulations relevant to a matter in controversy in an appeal before the Board and to grant the right to expedited judicial review ("EJR"). 42 U.S.C. § 139500(f)(1). Congress enacted the EJR provision to provide for immediate judicial review for matters where the Board lacks power to "grant the relief sought" and thereby avoid the delay inherent in "requiring providers to pursue a time-consuming and irrelevant administrative review merely to have the right to bring suit in a U.S. District Court." H.R. Rep. No. 96-1167, at 394 (1980), reprinted in 1980 U.S.C.C.A.N. 5526, 5757. Pursuant to the Secretary's regulations, the Board is bound by agency rules and rulings, like the 2023 rule at issue. 42 C.F.R. § 405.1867. Accordingly, the statute allows a hospital to request a Board determination as to its authority to decide a question of law or regulations and to initiate an action in this Court if the Board determines that EJR is appropriate. See 42 U.S.C. § 139500(f)(1).

The Presumption Against Retroactivity and the Medicare Statute's Retroactivity Provision

22. Retroactive rulemaking is disfavored in the law, and unless provided for expressly, statutes granting administrative agencies the authority to engage in rulemaking should be construed as extending that authority prospectively only. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Landgraf v. USI Film Prods.*, 511 U.S. 244, 245 (1994); *Republic of Austria v. Altmann*, 541 U.S. 677, 696 (2004) ("The aim of the [anti-retroactivity] presumption is

to avoid unnecessary post hoc changes to legal rules on which parties relied in shaping their primary conduct.") *cf. Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2288 (2024) (Gorsuch, J., concurring) (criticizing *Chevron* for allowing agencies to "replace one 'reasonable' interpretation with another at any time, all without any change in the law itself" with "[t]he result: [a]ffected individuals 'can never be sure of their legal rights and duties'" (citation omitted)).

23. In 1988, the Supreme Court addressed retroactive rulemaking in the Medicare context, holding in Bowen that the agency could not exercise its rulemaking authority to issue regulations limiting Medicare reimbursement retroactively. 488 U.S. at 215. In reaching that conclusion, the Supreme Court observed that "[r]etroactivity is not favored in the law," and that "congressional enactments and administrative rules will *not* be construed to have retroactive effect unless their language requires this result." Id. at 208 (emphases added). The Court added that "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." Id. In his concurrence, Justice Scalia explained that rules are applied retroactively if they "alter[] the past legal consequences of past actions," and that when the Secretary there prescribed "a formula for costs reimbursable while the prior rule was in effect, she changed the law retroactively." Id. at 219–20 (Scalia, J., concurring). Justice Scalia added that a rule that exclusively regulates future behavior may yet be invalid as arbitrary and capricious under the APA if it "makes worthless substantial past investment incurred in reliance upon the prior rule." Id. at 220. He explicitly rejected the Secretary's contention that "the evils generally associated with retroactivity do not apply to reasonable 'curative' rulemaking—that is, the correction of a mistake in an earlier rulemaking proceeding"—as "ha[ving] no basis in the law," and emphasized that he "would assuredly not sanction 'curative' retroactivity." Id. at 225. Notably, Justice Scalia opined that permitting such "curative" rulemaking "would 'make a mockery . . . of the APA,' since 'agencies would be free to violate the rulemaking requirements of the APA with impunity if, upon invalidation of a rule, they were free to "reissue" that rule on a retroactive basis." *Id.* (alteration in original) (citation omitted).

- 24. Later, in 1994, the Supreme Court observed that "[t]he presumption against statutory retroactivity is founded upon elementary consideration of fairness dictating that individuals should have an opportunity to know what the law is and to conform their conduct accordingly." *Landgraf*, 511 U.S. at 245. The Court explained that "the antiretroactivity principle finds expression in several provisions of our Constitution," including the Ex Post Facto and Due Process Clauses as well as the prohibitions on Bills of Attainder. *See id.* at 266. The Court added that even if the "retroactive application of a new statute would vindicate its purpose more fully[,]...[t]hat consideration... is not sufficient to rebut the presumption against retroactivity" because "[s]tatutes are seldom crafted to pursue a single goal" and "[a] legislator who supported a prospective statute might reasonably oppose retroactive application of the same statute." *Id.* at 285–86.
- 25. As is relevant here, in 2003, Congress enacted 42 U.S.C. § 1395hh(e)(1), which prohibits the agency from retroactively effectuating rules or policies adopting new substantive standards "unless the Secretary determines that" one of two very narrow exceptions are met, namely, when "such retroactive application is necessary to comply with statutory requirements," *id.* § 1395hh(e)(1)(A)(i), or where the "failure to apply the change retroactively would be contrary to the public interest," *id.* § 1395hh(e)(1)(A)(ii).
- 26. Congress enacted this provision expressly to limit CMS's power to undertake retroactive rulemaking. Before this 2003 amendment, the Medicare Act was silent regarding

retroactive rulemaking. Despite Supreme Court precedent imposing a presumption against retroactivity when statutes are silent, CMS continued to engage in such retroactive rulemaking. Industry leaders complained to Congress that "[h]ome care has faced great difficulties in the past with policy issued with retroactive impact, such as the revision in standards for allowable branch offices." The Medicare Regulatory and Contracting Reform Act of 2001: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 100th Cong. 54 (2001) (statement of Susan Wilson, Vice President, Clinical Operations, and Chief Operating Officer, VNA of Central Connecticut, Inc., New Britain, Connecticut; President, Board of Directors, Connecticut Association for Home Care, Wallingford, Connecticut; and Member, National Association for Home Care testifying about 2001 proposed text, which mirrored text adopted in 2003). Aware that CMS was exploiting the Medicare Act's silence to make retroactive changes in substantive payment standards, Congress responded in 2003 by enacting section 1395hh(e)(1) to "ensure that Medicare's rules are not generally applied retroactively." H.R. Rep. No. 108-74(I), at 42 (2003) (Conf. Rep.); Medicare Regulatory and Contracting Reform Act of 2001, Hearing on H.R. 3391 before the House of Representatives, 107th Con. 8793 (2001) (statement of Rep. Nancy Lee Johnson) (legislative history to Medicare retroactive rulemaking provision stating that the provision was intended to "prohibit[] the government from reimposing regulations retroactively" and from "changing the rules of the game and then punishing providers for noncompliance").

27. The Medicare statute also provides that "a substantive change . . . shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published . . . the substantive change." 42 U.S.C. § 1395hh(e)(1)(B)(i). The statute, however, permits the change to take effect before that 30-day period "if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of

such 30-day period is contrary to the public interest." *Id.* § 1395hh(e)(1)(B)(ii). The Medicare statute further states that "[n]o action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change." *Id.* § 1395hh(e)(1)(C).

28. In addition, the Medicare statute and implementing regulations provide for finality of claims payment determinations by restricting the untimely reopening and revision of a claim payment determination. See 42 U.S.C. § 1395gg(c); 42 C.F.R. § 405.980(b). In particular, the "without fault" provision of the Medicare statute provides that, absent a showing of fault, the agency may not recoup an alleged overpayment from a hospital more than five years after an initial payment determination was made. See 42 U.S.C. § 1395gg(c). As the Medicare Financial Management Manual explains, Congress deems such recovery to be "against...good conscience":

There are special rules that apply when an overpayment is discovered subsequent to the fifth year following the year in which notice was sent that the amount was paid. Ordinarily, the provider or beneficiary will be considered without fault unless there is evidence to the contrary. In the absence of evidence to the contrary, the [Medicare Administrative Contractor] will not recover the determined overpayment.

Medicare Financial Management Manual, CMS Pub. 100-06, ch. 3, §§ 70.3, 80, http://www.cms.gov/manuals/downloads/Fin106c08.pdf. Initial claims payment determinations are otherwise subject to reopening for four years, but following that period, they cannot be revised in the absence of fraud or similar fault, a clerical error that was unfavorable to the beneficiary or hospital, or as necessary pursuant to other statutes and regulations governing appeals. *See* 42 C.F.R. § 405.980(b).

Medicare Part C

29. Section 4001 of the Balanced Budget Act of 1997, Pub. Law No. 105-33, added a new Part C to the Medicare statute to establish a Medicare program that was originally called the

Medicare+Choice (also known as "M+C") program and is now called Medicare Advantage. A Medicare beneficiary can elect to receive Medicare benefits either through the original fee-for-service program under Medicare Parts A and B, or through enrollment in a Medicare Advantage plan under Medicare Part C. 42 U.S.C. § 1395w-21(a)(1); 42 C.F.R. § 422.50; *see also* 63 Fed. Reg. 34,968, 34,968 (June 26, 1998) ("Under section 1851(a)(1), every individual entitled to Medicare Part A and enrolled under Part B . . . may elect to receive benefits through *either* the existing Medicare fee-for-service program or a Part C M+C plan." (emphasis added)).

30. "Before 2004, [Defendant's agency] had not treated Part C enrollees as 'entitled to benefits under Part A." Allina II, 863 F.3d at 939 (quoting Northeast Hosp., 657 F.3d at 15); see also Allina I, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as not entitled to benefits under Part A."); Allina I, 904 F. Supp. 2d at 78-80; Northeast Hosp., 657 F.3d at 16-17. That approach reflected the original 1986 DSH regulation, which limited Part-A-entitled days in the Medicare Part A/SSI fraction to patient days that were "covered," or paid, by Medicare Part A. See 42 C.F.R. § 412.106(b)(2)(i) (2003); 42 C.F.R. § 409.3 (defining "covered" as services for which payment is authorized). The agency said as much when adopting the pre-2004 regulation, explaining that the numerator of the Medicare Part A/SSI fraction included only "covered Medicare Part A inpatient days." 51 Fed. Reg. at 16,777 (emphasis added); see also 51 Fed. Reg. 31,454, 31,460–61. Although the 1986 regulation did not expressly mention Part C patient days (as noted above, Part C came later), it necessarily excluded them as days not covered and paid under Part A. See Cath. Health Initiatives Iowa Corp. v. Sebelius, 718 F.3d 914, 921 n.5 (D.C. Cir. 2013) (noting that the pre-2004 regulation limited the Medicare Part A/SSI fraction to "covered Medicare Part A inpatient days" (citing 51 Fed. Reg. at 16,777)). The DSH regulation prior to 2004 necessarily excluded Part C days from Part-A-entitled days because Part C days are

not covered or paid under Part A. See 42 U.S.C. § 1395w-21(a)(1), (i) (providing that payment of Part C benefits is in lieu of benefits otherwise payable under Part A); see also Northeast Hosp., 657 F.3d at 6. The agency asserted incorrectly during the rulemaking at issue here that it was required to issue this 2023 rule because it had no preexisting, relevant promulgated rule. See 85 Fed. Reg. 47,723, 47,725 (Aug. 6, 2020); 88 Fed. Reg. 37,772, 37,776 (June 9, 2023). To the contrary, the agency had no obligation to engage in further notice and comment because it had already established the relevant DSH payment standard calling for the exclusion of Part C days from Part-A-entitled days, embodied in the 1986 regulation, through notice-and-comment rulemaking.

31. Further, written guidance prior to 2004 repeatedly expressed the agency's policy that Part C days, as days for which patients were not entitled to Part A payment, were to be excluded from Part-A-entitled days in the Medicare Part A/SSI fraction. *See Northeast Hosp.*, 657 F.3d at 15 (describing prior instructions not to submit information related to services furnished to Part C patients that would have been necessary to count Part C days in the Medicare Part A/SSI fraction). This guidance included instructions to hospitals and program memoranda transmitting the Medicare Part A/SSI fractions on an annual basis. *See* HCFA Pub. 60A, Transmittal No. A-98-36 (Oct. 1, 1998), *reprinted in* MEDICARE & MEDICAID GUIDE ("MMG") (CCH) ¶ 150,103 (transmitting Medicare Part A/SSI fractions that excluded Part C days, specifying that the fractions include only "covered Medicare days," and referring to the ratio of SSI days and "covered Medicare days" as "the ratio of Medicare Part A patient days attributable to SSI recipients"); HCFA Pub. 60A, Transmittal No. A-99-42 (Sept. 1, 1999), *reprinted in* MMG ¶ 150,769 (same); HCFA Pub. 60A, Transmittal No. A-00-54 (Aug. 17, 2000), *reprinted in* MMG ¶ 151,363 (same); CMS Pub. 60A, Transmittal No. A-01-109 (Sept. 13, 2001), *reprinted in* MMG ¶ 152,216 (same);

CMS Pub. 60A, Transmittal No. A-02-086 (Sept. 11, 2002), reprinted in MMG ¶ 152,922 (same); CMS Pub. 60A, Transmittal No. A-03-067 (Aug. 8, 2003), reprinted in MMG ¶ 153,554 (same); CMS Pub. 100-04, Transmittal 275 (Aug. 13, 2004), reprinted in MMG ¶ 154,468 (same).

- 32. In a 2003 proposed rule, the agency proposed "to clarify" its long-held position that "once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should not be included in the Medicare fraction of the DSH patient percentage." 68 Fed. Reg. 27,154, 27,208 (May 19, 2003). The agency explained that "[t]hese days should be included in the count of total patient days in the Medicaid fraction (the denominator), and the patient's days for a [Part C] beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction." *Id.* It also explained that "once a beneficiary has elected to join [a Part C] plan, that beneficiary's benefits are no longer administered under Part A." *Id.*
- 33. In a final rule published in August 2004, however, the agency engaged in a "volteface" and "abruptly announced a change in policy." *Allina I*, 746 F.3d at 1107–10; *Allina I*, 904 F. Supp. 2d 75, 78 (D.D.C. 2012); *see Northeast Hosp.*, 657 F.3d at 15–16 (finding that the agency's "actual treatment of [Part C] days" as well as its "statements in the 2004 rulemaking and in a subsequent 2007 technical revision confirm that [it] changed [its] interpretation of the DSH provision in 2004," and "belie[d] [its] claim that" the 2004 rule merely "codified a longstanding policy"). That 2004 rule announced that the agency would "adopt[] a policy" to include Part C days in the Medicare Part A/SSI fraction and exclude them from the Medicaid fraction effective October 1, 2004. 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004); *see also Northeast Hosp.*, 657 F.3d at 16 ("[I]n the 2004 rulemaking [the agency] announced that [it] was 'adopting a policy' of counting [Part C] days in the Medicare fraction.").

- 34. In the 2004 final rule, the agency purported to amend the regulation text by deleting the word "covered." 69 Fed. Reg. at 49,246. When the agency initially transmitted the Medicare Part A/SSI fractions for FFYs 2005 and 2006, however, those fractions continued to exclude Part C days. *See* CMS Pub. 100-04, Transmittal 1091 (Oct. 27, 2006), *reprinted in* MMG ¶ 156,277 (transmitting FFY 2005 Medicare Part A/SSI fractions and specifying that the fractions include only "covered Medicare days," and referring to the ratio of SSI days and "covered Medicare days" as "the ratio of Medicare Part A patient days attributable to SSI recipients"); CMS Pub. 100-04, Transmittal 1396 (Dec. 14, 2007), *reprinted in* MMG ¶ 156,930 (same for FFY 2006 fractions).
- 35. In July 2007, the agency issued a revision to a Medicare program manual, with a "purported 'effective date' of October 1, 2006," that permitted hospitals to submit the data necessary to implement the new policy regarding Part C days. Allina I, 904 F. Supp. 2d at 82. That same month, the agency also issued a transmittal instructing hospitals "to submit 'no pay' bills to their Medicare contractor for the [Part C] beneficiaries they treat, in order for these days to be eventually captured in the DSH . . . calculations." CMS Pub. 100-04, Transmittal 1311 at 1 (July 20, 2007), https://www.cms.gov/regulations-and-guidance/guidance/transmittals/ downloads/r1311cp.pdf; 88 Fed. Reg. at 37,789-90 (discussing Transmittal 1311); Northeast Hosp., 657 F.3d at 15 (describing this instruction as "the Secretary revers[ing] course"). Thereafter, in August 2007, the agency further amended the text of the DSH regulation governing Part C days without affording hospitals prior notice or opportunity for comment. 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007). Following the amendments in 2004 and 2007, the regulation provided that the Medicare Part A/SSI fraction includes all patient days (not just "covered" days) for "patients entitled to Medicare Part A (or Medicare Advantage (Part C))." Id. at 47,411 (amending §§ 412.106(b)(2)(i)(B) and (iii)(B)) (emphasis added). The amendment of the

regulation was made effective October 1, 2007, the beginning of FFY 2008. *Id.* at 47,130; *see also Allina I*, 904 F. Supp. 2d at 82. The agency further amended the regulation "in 2010 to use the word 'including' in place of 'or,' in an apparent attempt to bolster further" the agency's position on the treatment of Part C days. *Allina I*, 904 F. Supp. 2d at 82 n.5.

36. In May 2013, while the agency's appeal from this Court's decision in *Allina I* was pending before the Court of Appeals, the agency engaged in a new rulemaking on the treatment of Part C days effective only prospectively, beginning October 1, 2013. *See* 78 Fed. Reg. 27,486, 27,578 (May 10, 2013). In that rulemaking, the agency "in an abundance of caution . . . proposed to readopt the policy of counting the days of patients enrolled in [Part C] plans in the Medicare fraction " 78 Fed. Reg. 50,496, 50,615 (Aug. 19, 2013). Accordingly, effective as of October 1, 2013, the rule governing the DSH calculation is the same as the 2004 rule had been. *See id.* at 50,619 (stating that rule "readopt[ion]" applies to "[F]FY 2014 and subsequent years" only). The agency did not claim in this rule that it had the authority to adopt the rule retroactively. *See id.* at 50,619–20.

Northeast Hospital

37. The agency's change to the DSH payment calculation first adopted in 2004 has given rise to substantial litigation. Initially, the agency attempted to apply the 2004 rule change retroactively to cost years prior to the October 1, 2004, effective date of the 2004 rule. On September 13, 2011, the Court of Appeals found that the agency's retroactive application of its current rule to periods prior to October 1, 2004, violated the Supreme Court's longstanding decision in *Bowen* because it "change[d] the legal consequences of treating low-income patients" and thus could not be applied retroactively. *See Northeast Hosp.*, 657 F.3d at 13–17. The Court held that "the Secretary's present interpretation, which marks a substantive departure from his

prior practice of excluding [Part C] days from the Medicare fraction, may not be retroactively applied" to the fiscal years at issue. *Id.* at 17. The agency did not claim in the 2004 rule, *see generally* 69 Fed. Reg. 48,916, or the *Northeast Hospital* litigation, that it had retroactive rulemaking authority to make this change, *see Northeast Hosp.*, 657 F.3d at 17 ("We are aware of no statute that authorizes the Secretary to promulgate retroactive rules for DSH calculations."); Def.'s Cross-Mot. for Summ. J., *Northeast Hosp.*, 699 F. Supp. 2d 81 (D.D.C. 2010) (No. 09-0180), ECF No. 15; Def.'s Reply Mem. in Supp. of Def.'s Mot. for Summ. J., *Northeast Hosp.*, 699 F. Supp. 2d 81 (D.D.C. 2010) (No. 09-0180), ECF No. 24; Br. of Appellant, *Northeast Hosp.*, 657 F.3d 1 (D.C. Cir. 2011) (No. 10-5163); Reply Br. of Appellant, *Northeast Hosp.*, 657 F.3d 1 (D.C. Cir. 2011) (No. 10-5163).

38. The Court also adopted the Secretary's position that the Medicare DSH statute is ambiguous and does not require any specific treatment of Part C days in the DSH calculation. *Northeast Hosp.*, 657 F.3d at 11. In particular, the Court concluded that "Congress has not clearly foreclosed the Secretary's interpretation that [Part C] enrollees are entitled to benefits under Part A," and that "[r]ather, it has left a statutory gap, and it is for the Secretary, not the court, to fill that gap." *Id.* at 13. Moreover, although the agency ultimately contended that the 2004 rule "codified a longstanding policy," the Court found that its "treatment of [Part C] days prior to 2004 belie[d] [that] claim." *Id.* at 15. The record confirmed, according to the Court, that "the Secretary routinely *excluded* [Part C] days from the Medicare fraction," and that "she changed her interpretation of the DSH provision in 2004." *Id.* at 15–16. The Court also rejected the agency's contention that its "routine[] fail[ure] to count [Part C] patient days in the Medicare fraction prior to 2004" was a "result of data system errors." *Id.* The Court found that argument "not convincing" given the agency's pre-2004 written guidance, its contemporaneous description of the 2004 rule as newly

"adopting a policy' of counting [Part C] days in the Medicare fraction," and its 2007 description of the 2004 rule as announcing a "policy change." *Id.* Finally, the Court explained that "the practical consequences of this dispute number in the hundreds of millions of dollars." *Id.* at 5.

- 39. In his concurrence, then Judge Kavanaugh found that the plain language of the statute unambiguously foreclosed the agency's interpretation because it "is sufficiently clear in establishing that a Part C beneficiary is not simultaneously entitled to benefits under Part A for any specific patient day." *Id.* at 24 (Kavanaugh, J., concurring). This is because, he explained, "entitlement" means "to have payment made," and "a Medicare patient enrolled in a Part C plan does not have the right 'to have payment made under, and subject to the limitations in, [Medicare] part A." *Id.* at 20. He noted that "[t]he only thing that unifies the Government's inconsistent definitions of this term is its apparent policy of paying out as little money as possible." *Id.* at 20 n.1. Like the majority, he similarly found that the agency "interpreted the statute as the Hospital does here" until 2004, when it "abruptly changed course, apparently because of an overriding desire to squeeze the amount of money paid to Medicare providers (and beneficiaries) in light of the country's increasingly precarious fiscal situation." *Id.* at 21. Judge Kavanaugh also emphasized that "this statute does not permit HHS to pursue fiscal balance on the backs of Medicare providers and beneficiaries in this way." *Id.*
- 40. The agency acquiesced in *Northeast Hospital* in June 2012 through TDL-12391. TDL 12391, 06-06-12 (June 12, 2012). The transmittal provided that in light of the *Northeast* decision, it required Medicare contractors to "include any disallowed patient days attributable to patients who were enrolled in a Medicare Part C Plan and also eligible for Medicaid for discharges occurring on or after January 1, 1999 through September 30, 2004 in the Medicaid fraction" of the DSH calculation. *Id.* at 1. The agency specified that this relief should be applied to any cost

reports that were not yet settled, as well as settled cost reports where the hospitals had filed proper appeals. *Id.* at 1–2.

Allina I

- 41. In July 2009, the agency first published Medicare Part A/SSI fractions for hospital cost reporting periods beginning in FFY 2007. These fractions were the first ones that ever included Part C days.
- 42. In *Allina I*, the plaintiff hospitals were among a group of hospitals that challenged the 2004 rule change through administrative appeals initiated in 2009, arguing that (1) the new Part C days policy was not the "logical outgrowth" of the 2003 proposed rule "clarifying" the agency's former policy, and (2) the rule was arbitrary and capricious because the agency's "cursory explanation in the 2004 Final Rule" failed to acknowledge its departure from past policy and practice and ignored the "financial impact" of that departure. *Allina I*, 904 F. Supp. 2d at 89, 83, 92–94.
- 43. On November 15, 2012, this Court agreed and held that the policy announced in the 2004 final rule regarding Part C days was not the logical outgrowth of the 2003 proposed rule. *Id.* at 89–92. This Court also held that the "cursory explanation in the 2004 Final Rule failed to meet the requirements of the APA" because "the Secretary[] fail[ed] to acknowledge her 'about-face," and "her reasoning for the change was brief and unconvincing." *Id.* at 93 (quoting *Northeast Hosp.*, 657 F.3d at 15). Accordingly, this Court concluded that "[t]he portion of the 2004 Final Rule . . . that announced the Secretary's interpretation of the Medicare Disproportionate Share Hospital Fraction, as codified in 2007 at 42 C.F.R. § 412.106(b)(2) and as further modified

¹ The agency did not even begin to collect "all the data necessary to implement its new policy until 2007," and the FFYs 2005 and 2006 Medicare Part A/SSI fractions did not include Part C days. *Allina I*, 904 F. Supp. 2d at 82.

in 2010, will be vacated, and the case will be remanded to the Secretary for further action consistent with this Opinion." *Id.* at 95. The Court also noted that the agency's argument that its then"current interpretation [was] entirely consistent with the past" was "clearly forestalled by *Northeast Hospital*" and was "also irregular legal gamesmanship, which wastes time and casts unfortunate doubt on counsel's credibility." *Id.* at 77–78 n.2. The Court added that "*Northeast Hospital* [did not] give room for a legally significant difference between practice and policy," and that, "[i]n fact, the appellate court went to pains to state the opposite." *Id.* at 88.

- 44. On April 1, 2014, the Court of Appeals affirmed this Court's *Allina I* decision on the merits, "agree[ing] with the district court that the Secretary's final rule was not a logical outgrowth of the proposed rule." 746 F.3d at 1109. The Court similarly found that the agency's argument "that the Secretary did *not* previously actually include Part C days in the Medicaid fraction . . . disregards [its] holding in *Northeast Hospital*, where [it] explicitly stated that the Secretary did have a prior practice of excluding Part C days from the Medicare fraction." *Id.* at 1108. In reaching its conclusion, the Court explained that "a party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, i.e., one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction." *Id.* Because this procedural failure was a sufficient basis to vacate the rule, the Court of Appeals did not reach the arbitrariness of the agency's explanation. *Id.* at 1111.
- 45. With respect to remedy, the Court of Appeals held that this Court "correctly concluded that vacatur was warranted." *Id.* The court reversed, however, a part of this Court's order that required "the Secretary to recalculate the hospitals' reimbursements 'without using the interpretation set forth in the 2004 Final Rule." *Id.* (quoting the Post-Judgment Order). The Court

of Appeals instead remanded, noting that the "question whether the Secretary could reach the same result" on remand as would have applied under the vacated rule "was not before the district court" and therefore this Court should have simply "remand[ed] after identifying the error." *Id.* at 1111.

<u>Allina II</u>

- 46. In mid-June 2014, 16 days after the Court of Appeals' mandate in *Allina I* vacating the 2004 rule, the agency published Medicare Part A/SSI fractions for FFY 2012, including Part C days for all hospitals in the country. The agency proceeded without notice or comment and provided no explanation at all for its decision to include Part C days in the Medicare Part A/SSI fractions for FFY 2012 but instead issued those fractions just as it had for prior years, as if the vacatur of that rule in *Allina I* had never happened. Certain plaintiff hospitals in the *Allina I* litigation filed a separate action in this Court challenging the 2014 determination. This Court granted the agency's motion for summary judgment. *Allina II*, 201 F. Supp. 3d 94 (D.D.C. 2016), which the hospitals appealed.
- 47. In 2017, the Court of Appeals unanimously reversed the District Court, agreeing with the hospitals that the agency "violated the Medicare Act by failing to provide for notice and comment" before readopting the 2004 policy. *Allina II*, 863 F.3d at 942. The Court of Appeals concluded that the Medicare Act, 42 U.S.C. § 1395hh(a)(2), required rulemaking for any "(1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services,'" and that the agency's issuance of the FFY 2012 Medicare Part A/SSI fractions including Part C days satisfied each of these factors. *Id.* at 943. The Court also found that the agency violated another provision of the Medicare Act, 42 U.S.C. § 1395hh(a)(4), which provides that "if a regulation includes 'a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking,' that provision may not

become legally operative until it has gone through notice-and-comment rulemaking." *Id.* at 945. The Court concluded that "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Id.*

- 48. On April 27, 2018, the government filed a petition for certiorari. *See* Pet. for Writ of Cert., *Allina II*, 587 U.S. 566 (2019) (No. 17-1484). Before providing reasons for the petition, the government recognized that "[i]t is extremely important that agencies rigorously observe applicable procedural requirements, to provide the requisite notice to regulated parties." *Id.* at 13. The government also asserted that "[t]he significant financial stakes in this particular context underscore that certiorari is warranted," highlighting that "the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between \$3 and \$4 billion in reimbursement for FY2005 through FY2013." *Id.* at 23.
- Appeals' ruling in *Allina II* as to the notice-and-comment requirement under 42 U.S.C. § 1395hh(a)(2). *Allina II*, 587 U.S. 566. The Supreme Court held that the agency's 2014 application of the 2004 Part C days policy was "at least" a statement of policy that changed or established a substantive legal standard governing payment for services, and thus required notice-and-comment rulemaking under section 1395hh(a)(2) of the Medicare statute. *Id.* at 571–80. The Court emphasized that "the public had a right to notice and comment *before* the government could adopt the policy at hand." *Id.* at 573 (emphasis added) (citation omitted). The Court also explained that the inclusion of Part C days in the Medicare fraction "makes the fraction smaller and reduces hospitals' payments considerably—by between \$3 and \$4 billion over a 9-year period, according to the government." *Id.* at 571. The Court further opined that the government "might have sought to argue," but in fact did not contend, that "the *statute* itself required it to court Part C patients in

the Medicare fraction" and instead "has insisted that the statute 'does not speak directly to the issue,' and thus leaves a 'gap' for the agency to fill." *Id.* at 583–84 (citations omitted). In addition, the Supreme Court did not disturb the Court of Appeals' ruling that the readopted 2004 policy is also invalid under 42 U.S.C. § 1395hh(a)(4) because the agency failed to engage in notice-and-comment rulemaking following the logical outgrowth failure of its vacated 2004 rule before making the policy take effect, *id.* at 1816, or "legally operative," *Allina II*, 863 F.3d at 945.

50. On September 4, 2019, this Court entered judgment in favor of the plaintiffs in *Allina II*. See Order, *Allina II*, No. 14-cv-1415 (D.D.C. Sept. 4, 2019), ECF No. 58. As part of its order, the District Court vacated the agency's 2014 publication of the FFY 2012 Medicare Part A/SSI fractions including Part C days. *Id.* at 2. A year later, on September 4, 2020, the plaintiffs in that case filed a motion to enforce the Court's earlier judgment. *See* Mot. Enforce J., *Allina II*, No. 14-cv-1415 (D.D.C. Sept. 4, 2020), ECF No. 60. On June 16, 2023, the *Allina II* plaintiffs filed a notice of supplemental authority notifying the Court of the agency's final action on Part C days, *see* Pls.' Notice of Suppl. Auth., *Allina II*, No. 14-cv-1415 (D.D.C. June 16, 2023), ECF No. 69, to which the government responded on June 28, 2023, *see* Def.'s Resp. to Pls.' Notice of Suppl. Auth., *Allina II*, No. 14-cv-1415 (D.D.C. June 28, 2023), ECF No. 70. On July 22, 2023, the Court denied the plaintiffs' motion to enforce judgment, concluding that the lawfulness of the agency's Part C final action "is a question for another day, and another suit." Mem. Order at 1, *Allina II*, No. 14-cv-1415 (D.D.C. July 22, 2023), ECF No. 71.

Allina III

51. While the *Allina II* litigation was underway, on December 5, 2014, the agency issued a notice that the plaintiff hospitals' appeals, along with the appeals from the other hospitals in the *Allina I* case, was "now before the Administrator of CMS for a determination of the appropriate statutory interpretation in the absence of the vacated 2004 rule to be used to calculate

the providers' DSH payment with respect to the treatment of the Part C days for [F]FY 2007." Pls.' Mem. in Opp'n to Def.'s Mot. to Dismiss Ex. 2, at 2, *Allina III*, No. 16-cv-150 (D.D.C. May 4, 2016), ECF No. 12-2.

- 52. On January 23, 2015, the plaintiff hospitals, along with the other *Allina I* plaintiffs, submitted comments in response to the agency's notification of review on remand. See Def.'s Mot. to Dismiss Ex. 7, at 4-7, Allina III, No. 16-cv-150 (D.D.C. Apr. 4, 2016), ECF No. 9-7 (CMS Administrator decision summarizing the plaintiff hospital's comments). Among other comments, the Allina I plaintiffs contended that the pre-2004 standard was reinstated by the vacatur of the 2004 rule, see Providers' Comments to CMS Adm'r on Remand, Allina Health Servs. v. Blue Cross Blue Shield Ass'n, PRRB Case Nos. 10-0165G et al. at 18-20 (Jan. 23, 2015), and that this standard could not be altered until the agency undertook notice-and-comment rulemaking, see id. at 21–30. They also argued that the agency's interpretation conflicts with Congressional intent, see id. at 30-34, and that the agency should interpret "entitled" consistently throughout the Medicare statute, see id. at 34–37. The Allina I plaintiffs further asserted that public interest favors applying the pre-2004 standard because they made financial decisions in reliance on expected DSH payments consistent with those made under the agency's unchanged policy in the years immediately following the 2004 rule, until FFY 2008 when the agency first implemented the change. See id. at 17, 37-43.
- 53. On December 2, 2015, the agency on remand reached the same conclusion as the (vacated) 2004 final rule and issued its "final administrative decision," concluding that "days associated with Medicare patients who are enrolled in a Part C plan are to be included in the numerator and denominator of the Medicare fraction." Def.'s Mot. to Dismiss Ex. 7, at 46, *Allina III*, No. 16-cv-150 (D.D.C. Apr. 4, 2016), ECF No. 9-7. The agency acknowledged, among other

things, the Court of Appeals' *Northeast Hospital* holding that "the phrase 'entitled to benefits under part A' is ambiguous." *Id.* at 24 (citation omitted).

- 54. On January 29, 2016, the plaintiff hospitals here along with the other *Allina II* plaintiffs initiated *Allina III* by filing a complaint within 60 days of the agency's remand decision to challenge that "final administrative decision" on remand. *See* Compl., *Allina III*, No. 16-cv-150 (D.D.C. Jan. 29, 2016).
- 55. On April 4, 2016, the government filed a partial motion to dismiss, alleging that *Allina I* only concerned the treatment of Part C days in the SSI fraction, and that the *Allina III* plaintiffs should be estopped from expanding their case to address both fractions. *See* Def.'s Mot. to Dismiss, *Allina III*, No. 16-cv-150 (D.D.C. Apr. 4, 2016), ECF No. 9.
- 56. On August 4, 2017, the Court issued an opinion denying the government's motion to dismiss. *See* Order, *Allina III*, No. 16-cv-150 (D.D.C. Aug. 4, 2017), ECF No. 16. The Court concluded that it had jurisdiction to hear the hospitals' challenge to the calculation of both fractions, citing the *Allina I* language that "the statute unambiguously requires that Part C days be counted in one fraction or the other." *Id.* at 17 (quoting *Allina I*, 746 F.3d at 1108 (emphasis omitted)). The Court also concluded that the hospitals were not judicially estopped from pursuing the Medicaid fraction challenge. *Id.* at 26.
- 57. Subsequently, the parties jointly agreed to stay briefing on the merits pending a final decision in *Allina II*, *see* Joint Status Report, *Allina III*, No. 16-cv-150 (D.D.C. Aug. 16, 2017), ECF No. 18, and the Court stayed the case, *see* Minute Order, *Allina III*, No. 16-cv-150 (D.D.C. Aug. 17, 2017).
- 58. On July 11, 2019, the *Allina III* plaintiffs filed a motion for judgment after the Supreme Court's decision in *Allina II*. *See* Pls.' Mot. for J., *Allina III*, No. 16-cv-150 (D.D.C. July

- 11, 2019), ECF No. 26. On July 25, 2019, the government opposed this motion and cross-moved for a remand to the agency to consider the implications on the case of the Supreme Court's decision. *See* Def.'s Response to Pls.' Mot. for J., *Allina III*, No. 16-cv-150 (D.D.C. July 25, 2019), ECF No. 27.
- 59. On October 25, 2019, the Court issued a decision denying the motion for judgment and granting the government's motion for a remand to the agency. *See* Order, *Allina III*, No. 16-cv-150 (D.D.C. Oct. 25, 2019), ECF No. 34. The Court remanded the challenge to the CMS Administrator decision at issue without vacating it. *Id.*; *see* Order at 2, *Allina III*, No. 16-cv-150 (D.D.C. Jan. 2, 2020), ECF No. 40 (clarifying that the October 2019 order "should not have referred to vacatur"); Order, *Allina III*, No. 16-cv-150 (D.D.C. Jan. 2, 2020), ECF No. 41 (amended October 2019 order).

Subsequent Rulemaking and Related Instructions

- 60. On August 6, 2020, nearly 16 years after CMS originally promulgated the now-vacated 2004 final rule, the agency published in the *Federal Register* a notice of proposed rulemaking announcing a proposal to adopt retroactively for periods prior to October 1, 2013 (and even prior to the vacated 2004 rule) the same Part C policy change as that previously adopted in the publications vacated in *Allina I* and *Allina II*. 85 Fed. Reg. 47,723.
- 61. The proposed rule claimed incorrectly that, due to the vacatur of the 2004 rule, the agency has no rule governing the treatment of Part C days and must, under the Supreme Court's opinion in *Allina II* requiring notice-and-comment rulemaking, engage in retroactive rulemaking. *Id.* at 47,724–25. The proposed rule, however, ignored the pre-2004 rule as well as the policy and practice reinstated by the 2004 rule's vacatur. *Id.* at 47,725.

62. The proposed rule claimed two grounds for its use of retroactive rulemaking: first, it claimed that retroactive rulemaking is necessary to establish a standard to comply with the statutory requirement to calculate Medicare DSH payments, and second, it claimed that retroactive rulemaking is in the "public interest" because, absent retroactive rulemaking, the agency "would be unable to calculate and confirm proper DSH payments for the time periods before [F]FY 2014." 85 Fed. Reg. at 47,725. As the agency has consistently argued in the litigation challenging the validity of its attempts to change its policy on Part C days in the DSH calculation, the agency did not assert in the proposed rule that the DSH statute was unambiguous as to Part C days and acknowledged the Court of Appeals holding that the term "entitled to benefits" under Part A in the DSH statute is ambiguous. See 85 Fed. Reg. at 47,725 (acknowledging that, in Northeast Hospital, "[t]he Court of Appeals . . . held that the Medicare statute does not speak directly to how Part C days should be treated for purposes of DSH calculations"); Def.'s Mot. for Summ. J. at 3, 10–11, 14, 44, *Allina I*, 904 F. Supp. 2d 75 (D.D.C. 2012) (No. 10-1463), ECF No. 35; Def.'s Reply Mem. in Supp. of Mot. for Summ. J. at 7, Allina I, 904 F. Supp. 2d 75 (D.D.C. 2012) (No. 10-1463), ECF No. 40; Br. for Appellant Kathleen Sebelius at 10, Allina I, 746 F.3d 1102 (D.C. Cir. 2014) (No. 13-5011); Final Br. for Appellant Kathleen Sebelius at 10, 22, Allina I, 746 F.3d 1102 (D.C. Cir. 2014) (No. 13-5011); Final Reply Br. for Appellant Kathleen Sebelius at 23, Allina I, 746 F.3d 1102 (D.C. Cir. 2014) (No. 13-5011); Def.'s Mot. for Summ. J. at 9–10, 19, 21, 23, Allina II, 201 F. Supp. 3d 94 (D.D.C. 2016) (No. 14-1415), ECF No. 29; Reply Mem. of Points & Authorities in Support of Def.'s Mot. for Summ. J. at 9, 11, Allina II, 201 F. Supp. 3d 94 (D.D.C. 2016) (No. 14-1415), ECF No. 33; Br. for Appellee Thomas E. Price, M.D. at 19, Allina II, 863 F.3d 937 (D.C. Cir. 2017) (No. 16-5255); Final Br. for Appellee Thomas E. Price, M.D. at 10, Allina II, 863 F.3d 937 (D.C. Cir. 2017) (No. 16-5255); Reply Br. for Pet'r 5 n.3, Allina II, 587 U.S. 566 (2019) (No.

17-1484); Def.'s Reply in Supp. of Mot. for Voluntary Remand 8, *Allina II*, 2020 WL 7042869 (D.D.C. Jan. 2, 2020) (No. 16-0150), ECF. No. 32; Def.'s Mot. for Leave to File Sur-Reply to Pls.' Mot. for Summ. J. 7–8, *Fla. Health Scis. Ctr. v. Becerra*, 2021 WL 2823104 (D.D.C. July 7, 2021). The agency notably did not address in the proposed rule the Ninth Circuit's decision in *Empire Health Foundation for Valley Hospital Medical Center v. Azar*, which on May 2, 2020, found substantively invalid the agency's 2005 rule regarding the counting of patient days in the Medicare fraction of individuals who were eligible for Medicare Part A and Medicaid but not entitled to have payment made for such days under the Medicare Part A payment system. 958 F.3d 873, 884–86 (9th Cir. 2020), *rev'd and remanded sub nom. Becerra v. Empire Health Found., for Valley Hosp. Med. Ctr.*, 597 U.S. 424 (2022).

63. On June 9, 2023, the agency issued its "final action" on remand in the form of the 2023 rule. See 88 Fed. Reg. at 37,786. CMS finalized its proposal to adopt retroactively for all periods prior to October 1, 2013, the same Medicare DSH payment standard change on Part C days in the DSH calculation reflected in the prior publications vacated in Allina I and Allina II, see id. at 37,790, as well as the prospective-only 2013 rule, see id. at 37,792 ("[I]n this final action we are adopting the same policy of including [Part C] patient days in the Medicare fraction that was prospectively adopted in the FY 2014 IPPS final rule and applying this policy retroactively to any cost reports that remain open for cost reporting periods starting before October 1, 2013."). The agency newly claimed—inconsistent with the proposed rule—that its interpretation of the DSH statute as to Part C days is statutorily required following the Supreme Court's decision on a different category of days in Empire Health. See id. at 37,775. The agency also asserted, in the alternative, that its retroactive rulemaking is necessary and proper to comply with the Supreme Court's decision in Allina II and "to establish" the Part C standard for cost years before October 1,

2013. Id. at 37,776; see 88 Fed. Reg. at 37,772 ("This final action establishes a policy"); id. at 37,774 ("[I]t is necessary for CMS to engage in retroactive rulemaking to establish a policy "); id. at 37,783 ("If rulemaking was required to change the Secretary's approach, as held in Allina II, then rulemaking was also required to establish the Secretary's approach in the first place."). The agency also justified such retroactive rulemaking by suggesting that the action (1) was needed to cover the "avowed statutory gap" following *Empire*, id. at 37,781, and (2) served the public interest by "avoid[ing] the consequences of ambiguity" in DSH payment calculations, id. at 37,790. Moreover, the agency claimed both that "Medicare DSH payments have already been made under the policy reflected in the proposal," id., and that this rule was needed "to avoid the consequences of legal ambiguity" because CMS otherwise "would be unable to calculate and confirm proper DSH payments for time periods before [F]FY 2014," id. at 37,775. With respect to the financial impact, the agency stated that this rule "does not have any additional costs or benefits relative to the Medicare DSH payments that have already been made," id. at 37,772, including for "small rural hospitals," id. at 37,793. CMS also claimed that while "[i]t is not clear what to compare an estimate of DSH payments [to] under [the] final policy," the agency "estimate[s] [that] the change in Medicare DSH payments to hospitals as a result of the policy finalized in this action based on a range of potential expenditures" is "\$0-\$0.6 billion." Id. Following this final agency action in the final rule, plaintiff hospitals here once again joined the other Allina hospitals to challenge the rule for their cost years beginning in 2007. See Compl., Allina Health Sys. v. Becerra, No. 1:23-cv-02144 (D.D.C. July 24, 2023) ("Allina IV"), ECF No. 1. The district court in Allina IV dismissed the suit without prejudice for lack of subject-matter jurisdiction, explaining that the plaintiffs "will be able to pursue their challenge to the 2023 Rule after they have properly presented their claims to the Secretary and exhausted their administrative

remedies." See Mem. Op. at 13-15, Allina IV, No. 1:23-cv-02144 (D.D.C. Sept. 27, 2024), ECF No. 24.

64. On February 1, 2024, CMS published instructions to Medicare contractors to implement the 2023 rule. *See* Change Request (CR) to Implement the Medicare Program Final Action: Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage, CMS Manual System, Pub. 100-20, Transmittal 12513, CR 13294 (Feb. 1, 2024), https://www.cms.gov/files/document/r12513otn.pdf (hereinafter "CR 13294"). Among other things, CMS instructed Medicare contractors to issue revised NPRs for appeals of pre-October 1, 2013, cost reporting periods that have been remanded pending the resolution of *Allina II*. *Id*.

FACTS SPECIFIC TO THIS CASE AND THE PROCEDURAL POSTURE

- 65. Following the publication of CMS's February 1, 2024, instructions, the plaintiff hospitals received NPRs applying the June 2023 final action for the cost reporting periods at issue. Each of the plaintiff hospitals timely filed an appeal to the Board expressing its dissatisfaction with the treatment of Part C days as Part A-entitled days in the DSH payment under the June 2023 final action and contesting the determination of the DSH payment amount due for its cost years at issue on the ground that Part C days were incorrectly counted in the Medicare DSH calculation. The Board assigned those appeals the following case numbers: Case No. 17-2193 (Montefiore 2005); Case No. 24-2440 (Montefiore 2007); Case No. 24-2489 (Montefiore 2008); Case No. 24-2485 (New York Methodist 2009); Case No. 24-2487 (New York Methodist 2010); Case No. 24-2488 (New York Queens 2011); and Case No. 24-2495 (New York Queens 2012).
- 66. Plaintiff hospitals in those appeals requested EJR of the validity of the June 2023 rule. By letters dated August 22, 2024 (Montefiore 2005), September 25, 2024 (Montefiore 2007)

and Montefiore 2008), and September 26, 2024 (New York Methodist 2009, New York Methodist 2010, New York Queens 2011, New York Queens 2012), the Board granted plaintiff hospitals' EJR requests. In its letters, the Board found that it had jurisdiction to hear plaintiff hospitals' appeals under 42 U.S.C. § 139500(f)(1) and 42 C.F.R. §§ 405.1835(a), 405.1889(b). The Board then granted the hospitals' EJR requests because the Board "is without the authority to decide the legal question of whether the DSH Part C Days policy, as adopted on a retroactive basis in the June 2023 Final Rule" is "substantively or procedurally valid."

67. By the filing of this Complaint, the plaintiff hospitals have properly commenced this action for judicial review under 42 U.S.C. § 139500(f)(1).

ASSIGNMENT OF ERRORS

- 68. The Medicare statute provides for judicial review of the questions presented here "pursuant to the applicable provisions under chapter 7 of title 5," *i.e.*, the APA. 42 U.S.C. § 1395oo(f)(1).
- 69. The applicable provisions of the APA provide that the "reviewing court shall . . . hold unlawful and set aside agency action . . . found to be . . . (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; [or] (E) unsupported by substantial evidence." 5 U.S.C. § 706(2). Under this standard, the 2023 rule is invalid, and should be set aside, because the agency's readoption of the Part C policy first published in the 2004 rule that the plaintiff hospitals already challenged before the agency and succeeded in getting vacated and then readopted prospectively in the 2013 rule during the course of the *Allina* litigation is arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law, in excess of statutory authority, without observance of procedure required

by law, and unsupported by substantial evidence, including for (but not limited to) the reasons more specifically described below.

Count I: The Final Action Should Be Set Aside as Contrary to Law and Required Procedure, and In Excess of Statutory Authority

- 70. The plaintiff hospitals repeat the allegations in paragraphs 1–69 of this Complaint as if fully set forth herein.
- 71. The final action again misconstrues the legal landscape following Allina I and Northeast Hospital, and the agency now unlawfully asserts authority to adopt retroactively its previously prospective-only 2013 rule. The Court of Appeals' decision in Allina I, finding that the 2004 final rule was not a logical outgrowth of the proposed rule, restored the pre-existing DSH policy and practice of not including Part C days as Part-A-entitled days. See 746 F.3d at 1105; United Steel v. Mine Safety & Health Admin., 925 F.3d 1279, 1287 (D.C. Cir. 2019) (finding that because the new rule "modifie[d]" a pre-existing standard, the effect of vacatur was to "automatically resurrect[]" the prior standard); Croplife Am. v. EPA, 329 F.3d 876, 879 (D.C. Cir. 2003) (explaining that "[a]s a consequence" of vacating a rule, "the agency's previous practice . . . is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation" (emphasis added)); Action on Smoking & Health v. C.A.B., 713 F.2d 795, 797 (D.C. Cir. 1983) ("[B]y vacating or rescinding the re[s]cissions . . . the judgment of this court had the effect of reinstating the rules previously in force" (citations omitted)). The agency ignores the legal effect of the restored pre-2004 DSH standard. And given that CMS already established the relevant standard, embodied in the 1986 regulation, through notice-and-comment rulemaking, the agency need not, as it claims, engage in further notice and comment to establish such a standard. See 88 Fed. Reg. at 37,776; supra ¶ 29. The 2023 rule also conflicts with the finding of this Court in Allina I that the agency's argument that its 2004 "interpretation [was] entirely

consistent with the past" was "clearly forestalled by *Northeast Hospital*" and was "also irregular legal gamesmanship, which wastes time and casts unfortunate doubt on counsel's credibility." 904 F. Supp. 2d at 77–78 n.2. The agency engages in this same "gamesmanship" that was "forestalled" by *Allina I* and *Northeast Hospital*. *Id*.

- 72. The exclusion of Part C days from the numerator of the Medicaid fraction for any patients discharged prior to October 1, 2004, also contradicts the Court of Appeals' decision in Northeast Hospital, which found that the agency could not retroactively apply the 2004 policy change to periods prior to the October 1, 2004, effective date of that rule. 657 F.3d at 16–17. The agency's attempt to apply this policy again through the 2023 rule runs directly afoul of the Northeast Hospital decision. As with the 2004 rule, the agency continues to ignore Northeast Hospital and to deny the change in policy that it established. See 88 Fed. Reg. 37,783 ("recogniz[ing] that . . . Northeast stated . . . that the agency had a pre-[F]FY 2005 'practice' of excluding Part C days from the Medicare fraction, but" asserting "that case did not hold that this practice amounted to a policy"). But in Northeast Hospital, the Court of Appeals rejected the agency's contention that its decision not to count Part C days as Part-A-entitled prior to implementing the 2004 rule was a "result of data system errors" because of the agency's pre-2004 written guidance, its contemporaneous description of the 2004 rule as newly "adopting a policy' of counting [Part C] M + C days in the Medicare fraction," and its 2007 description of the 2004 rule as announcing a "policy change." 657 F.3d at 15–16 (citations omitted).
- 73. The final action also violates the language and intent and has exceeded the authority of 42 U.S.C. § 1395hh(e). Neither of the narrow exceptions permitting "retroactivity of substantive changes" applies, and the agency itself in the recent rulemaking purports to "establish" a policy rather than "change" its policy on Part C days. *See* 42 U.S.C. § 1395hh(e)(1)(A); *see* 88

Fed. Reg. at 37,772, 37,774, 37,776, 37,783. Section 1395hh(e) prohibits the agency from retroactively applying "substantive change[s]" in Medicare "regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability" unless the agency determines that one of two very narrow exceptions are met, namely, when "such retroactive application is necessary to comply with statutory requirements," *id.* § 1395hh(e)(1)(A)(i), or where the "failure to apply the change retroactively would be contrary to the public interest," *id.* § 1395hh(e)(1)(A)(ii). These limited exceptions do not apply here.

The first narrow "required by statute" exception cannot be met here because the 74. Court of Appeals has expressly adopted Defendants' prior position that the DSH statute is ambiguous, and the statute does not require any specific treatment of Part C days in the DSH calculation. See Northeast Hosp., 657 F.3d at 11 ("The Secretary points us to other provisions that assume it is possible to be both entitled to benefits under Part A and enrolled in Part C. [W]e conclude that the Medicare statute does not unambiguously foreclose the Secretary's interpretation."); see Allina I, 746 F.3d at 1106 ("[T]he phrase 'entitled to benefits under Part A' is ambiguous." (citation omitted)). The government has consistently taken that position. See, e.g., Def.'s Mot. for Summ. J. at 3, 10–11, 14, 44, Allina I, 904 F. Supp. 2d 75 (D.D.C. 2012) (No. 10-1463), ECF No. 35; Def.'s Mot. for Summ. J. at 9–10, 19, 21, 23, Allina II, 201 F. Supp. 3d 94 (D.D.C. 2016) (No. 14-1415); supra \P 62. The agency did not assert in the proposed rule that the statute unambiguously required its interpretation. See 85 Fed. Reg. 47,725 (claiming that it met the "required by statute" exception permitting retroactive applicability of a substantive change because "to comply with the statutory requirement to make DSH payments, it is necessary for CMS to engage in retroactive rulemaking to establish a policy to govern" Part C days "for fiscal years before 2014"). Rather, the proposed rule acknowledged the Court of Appeals' holding that

the term "entitled to benefits" under Part A in the DSH statute is ambiguous. *See* 85 Fed. Reg. 47,725 (recognizing that, in *Northeast Hospital*, "[t]he Court of Appeals held that the Medicare statute does not speak directly to how Part C days should be treated for purposes of DSH calculations").²

75. Nor can the final action be justified as required by the statutory obligation to make DSH payments. See 88 Fed. Reg. at 37,777. Aside from the fact that the agency says payments have generally "already been made," id. at 37,790, as described above, the 1986 regulation limiting "entitled" days to "covered" Part A days permits the agency to calculate DSH payments by treating Part C days as not Part-A-entitled without any further rulemaking; only changing that policy requires rulemaking, see supra ¶ 29. And even assuming arguendo that the 1986 regulation were not to apply and some rulemaking were required, the obligation to calculate DSH payments would still not require *retroactive* rulemaking. The agency could codify its pre-existing (pre-2004) policy and practice of treating Part C days as not Part-A-entitled in a rulemaking without that rulemaking being retroactive. See Northeast Hosp., 657 F.3d at 15 (explaining that "[i]f a new rule is substantively inconsistent with a prior agency practice and attaches new legal consequences to events completed before its enactment, it operates retroactively" (alteration in original) (internal quotation marks and citation omitted). Only the new policy change (repeatedly attempted but never effected for pre-2013 cost years) is substantively inconsistent with prior policy and practice and thus retroactive. Accordingly, the agency could meet the statutory requirement to calculate

² To the extent that the agency asserts, contrary to *Northeast Hospital*, that its interpretation is compelled by the DSH statute, the plaintiff hospitals contend that the Part C days policy reflected in the 2023 rule is contrary to the plain language of the Medicare DSH statute. *See* 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I)–(II); *Northeast Hosp.*, 657 F.3d at 24 (Kavanaugh, J., concurring) (finding that the plain language of the statute unambiguously foreclosed the agency's interpretation because it "is sufficiently clear in establishing that a Part C beneficiary is not simultaneously entitled to benefits under Part A for any specific patient day").

DSH payments without retroactive rulemaking; it simply cannot apply its new policy of treating Part C days as Part-A-entitled without retroactivity. The agency's preference for that position does not make it a statutory obligation.

- 76. The agency's new reliance on *Empire Health* to suggest that the DSH statute requires its interpretation is misguided. First, the Court did not decide whether patients who have opted out of the Part A fee-for-service program to elect Part C coverage are still entitled to Part A—a fact that the agency concedes. *See* 88 Fed. Reg. 37,774 ("Empire did not address specifically whether Part C enrollees remain 'entitled to Part A " (citation omitted)). Second, while decided before *Loper Bright* overtured *Chevron*, *Empire Health* did not decide whether (or that) the agency's interpretation was unambiguously required by statute. Moreover, reading the DSH provisions of the Medicare statute as requiring retroactive rulemaking now, two decades after the agency's first failure at proper notice-and-comment rulemaking and a decade after its second such failure, would make a mockery of the heightened Medicare notice-and-comment rulemaking requirements in 42 U.S.C. § 1395hh(e)(1)(A).
- 77. The agency's interpretation in the 2023 rule of this limited exception is also inconsistent with its historical understanding of the exception to allow retroactive rulemaking to comply with a Congressionally mandated effective date of a payment change. *See, e.g.*, 73 Fed. Reg. 24,871 (May 6, 2008) (statutory change required agency to change the outlier payments and base rates; agency justified retroactive rulemaking because statute required implementation starting December 29, 2007); 73 Fed. Reg. 29,699, 29,707 (May 22, 2008) (statutory change required agency to issue three-year moratorium on new long-term care hospitals ("LTCHs") and increasing number of beds for existing LTCHs; agency justified retroactive rulemaking because statute required implementation starting December 29, 2007); 74 Fed. Reg. 43,754, 43,992–93

(Aug. 27, 2009) (agency made revisions to LTCH adjustment policies and revised the moratorium on bed increases in existing LTCHs, as directed by amendments to the implementing statute, and justified retroactive application because statute required various policy changes "beginning with cost reporting periods beginning on or after July 1, 2007, October 1, 2007, or December 29, 2007 as applicable").

78. The second limited exception is not met here because the 2023 rule cannot be said to be in the public interest. Among other reasons, it offends fundamental notions of justice and disregards the significant public interest in advance notice-and-comment rulemaking, especially where, as here, the agency has suffered defeat three times in the Court of Appeals and the Supreme Court over its policy change and, instead of paying safety-net hospitals what they are owed, unfairly seeks to readopt that same policy retroactively two decades after the agency first attempted to adopt the same change in its 2004 rule. See, e.g., Bowen, 488 U.S. at 225 (Scalia, J., concurring) (permitting "curative" rulemaking "would 'make a mockery . . . of the APA,' since 'agencies would be free to violate the rulemaking requirements of the APA with impunity if, upon invalidation of a rule, they were free to "reissue" that rule on a retroactive basis" (citation omitted)). The rule also results in thousands of safety-net hospitals losing billions of dollars in funding that has been illegally withheld for years. Indeed, the agency had historically recognized the limited nature of this public interest exception. For example, CMS has adopted the public interest exception to correct technical errors made in a prior rulemaking, see, e.g., 69 Fed. Reg. at 78,717; 70 Fed. Reg. at 16,729; 70 Fed. Reg. at 52,025; 70 Fed. Reg. at 76,176; 70 Fed. Reg. at 76,197; 72 Fed. Reg. at 18,913. CMS also invoked this exception in responding to a natural disaster when, following the Hurricane Katrina disaster in the Gulf Coast area, CMS retroactively changed the graduate medical education ("GME") full-time equivalent rules to account for

displaced residents forced to train at hospitals outside disaster zones, as well as to ensure consistent GME funding for hospitals within the disaster zone to ease hardship on hospitals caused by the hurricane. *See* 71 Fed. Reg. at 18,663. And as explained further below, the public interest counsels against applying the readopted policy from the vacated 2004 rule in the 2023 rule because hospitals nationwide, including the plaintiff hospitals, made financial decisions relying on DSH payments being consistent with the pre-2004 standard before the issuance of the 2007 SSI fractions in 2009 and following the 2012 vacatur of the rule in 2004 for periods prior to October 1, 2013. Finally, the 2023 rule conflicts with the legislative history of Section 1395hh(e), which confirms that Congress enacted this provision in 2003 to expressly *limit* CMS's power to continue engaging in retroactive rulemaking, not expand it. *See* H.R. Rep. No. 108-391, at 42 (2003) (Conf. Rep.) (enacting 1395hh(e)(1) to "ensure that Medicare's rules are *not* generally applied retroactively" (emphasis added)).

79. The final action also otherwise violates 42 U.S.C. § 1395hh(e)(1)(A). The agency claims to be "establish[ing]" a standard on Part C days. *See, e.g.*, 88 Fed. Reg. at 37,772 ("This final action establishes a policy[.]"); *id.* at 37,774 ("[I]t is necessary for CMS to engage in retroactive rulemaking to establish a policy[.]"); *id.* at 37,776 ("[T]he decision in *Allina II* would require notice-and-comment rulemaking to establish the gap-filling policy stated in this action."); *id.* at 37,783 ("If rulemaking was required to change the Secretary's approach, as held in *Allina II*, then rulemaking was also required to establish the Secretary's approach in the first place."). However, if that were the case, then the agency could not do so retroactively because section 1395hh(e)(1)(A) of the Medicare statute permits retroactive rulemaking only to "change" a substantive standard, not to "establish" one. *See* 42 U.S.C. § 1395hh(e)(1)(A).

- 80. To the extent that there were any ambiguity concerning whether the agency had the authority to engage in retroactive rulemaking under 42 U.S.C. § 1395hh(e) (and there is no such ambiguity) following Northeast Hospital and the subsequent vacatur of the 2004 rule in Allina I, any such ambiguity must be read against retroactivity. See Landgraf, 511 U.S. at 273 (explaining that the presumption against retroactivity does "no[t] conflict" with the principle that "a court should 'apply the law in effect at the time it renders its decision' . . . when the statute in question is unambiguous" (citation omitted) (emphasis added)); I.N.S. v. St. Cyr, 533 U.S. 289, 320 (2001) (discussing the "the presumption against retroactive application of *ambiguous* statutory provisions" (emphasis added)); Coal. for Common Sense in Gov't Procurement v. U.S., 707 F.3d 311, 318 (D.C. Cir. 2013) ("As the Supreme Court has instructed, a 'statute may not be applied retroactively . . . absent a clear indication from Congress that it intended such a result." (quoting St. Cyr, 533 U.S. at 316)). Indeed, well-established case law disfavors retroactivity and provides for a "presumption against retroactivity." Landgraf, 511 U.S. at 245 (emphasis added). The Supreme Court has explained that "[r]etroactivity is not favored in the law. . . [such that] a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules." Bowen, 488 U.S. at 208. The Court has expressed that "[t]he presumption against statutory retroactivity is founded upon elementary consideration of fairness dictating that individuals should have an opportunity to know what the law is and to conform their conduct accordingly." Landgraf, 511 U.S. at 245.
- 81. The final action similarly violates the Medicare statute and implementing regulations, which preclude untimely reopening and revision of a claim payment determination. *See* 42 U.S.C. § 1395gg(c); 42 C.F.R. § 405.980(b). The Medicare statute specifically states that, absent a showing of fault, the agency may not recoup an alleged overpayment from a hospital more

than five years after an initial payment determination was made. *See* 42 U.S.C. § 1395gg(c). Here, no such fault has been, or can be, established. The agency thus cannot recoup such funds from the plaintiff hospitals that it paid under the pre-2004 standard. *See* Medicare Claims Processing Manual, ch. 3, § 20.3 ("[T]he [contractor] will identify hospitals that are eligible to receive the DSH adjustment and make interim payments subject to a year-end settlement based upon the hospital's DSH percentage for the cost reporting period."); 42 C.F.R. § 413.64(f)(2).

82. The rule also violates Allina II and is procedurally invalid under 42 U.S.C. § 1395hh(a). The Medicare Act provides that if a final rule is not a logical outgrowth of a proposed rule, then it "shall not take effect" until there is further opportunity for comment and publication again as a final rule. 42 U.S.C. § 1395hh(a)(4). After finding a logical outgrowth failure in Allina I, 746 F.3d at 1109, the Court of Appeals in Allina II concluded that the agency violated 42 U.S.C. § 1395hh(a)(4) by not providing a "further opportunity for public comment and a publication of the [2004] provision again as a final regulation" before reimposing or making "legally operative" the 2004 rule vacated for a logical outgrowth failure, 863 F.3d at 945. The Court held that the agency could not bypass the notice-and-comment requirements of the Medicare Act by claiming to proceed through adjudication, 863 F.3d at 945, which is an inherently retroactive process, see Bowen, 488 U.S. at 221 (Scalia, J., concurring) ("Adjudication deals with what the law was; rulemaking deals with what the law will be."). This means that the agency is barred from effectuating or applying the same policy change at least until after the effective date of a legally sound notice-and-comment process adopting the rule prospectively only. If the agency were allowed to proceed with the 2023 rule, it would render meaningless Section 1395hh(a)(4), as the agency could always circumvent the statute's advance notice-and-comment requirement by reimplementing the rule retroactive to the date of the initial rule that created the logical outgrowth

problem in the first place. But such rulemaking, as Justice Scalia opined in *Bowen*, "would 'make a mockery . . . of the APA,' since 'agencies would be free to violate the rulemaking requirements of the APA with impunity if, upon invalidation of a rule, they were free to 'reissue' that rule on a retroactive basis." 488 U.S. at 225 (Scalia, J., concurring).

83. The rule further violates *Allina II* and is procedurally invalid under 42 U.S.C. § 1395hh(a)(2). The Medicare Act requires notice-and-comment rulemaking for a "rule," a "requirement" or a "statement of policy" that "establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). In *Allina II*, the Supreme Court upheld the Court of Appeals' finding that the agency "violated" the rulemaking provisions of the Medicare Act under 42 U.S.C. § 1395hh(a)(2) by failing to provide for notice and comment. 587 U.S. at 571–79. The Court determined that the agency's attempted readoption of the 2004 policy was at least a statement of policy that changed or established a substantive legal standard governing payment for services, and thus required notice and comment under Section 1395hh(a)(2). *Id.* The Supreme Court emphasized that "the public had a right to notice and comment *before* the government could adopt the policy at hand." *Id.* at 573 (citation omitted and emphasis added). As with section 1395hh(a)(4), the 2023 rule cannot "take effect" *before* substantive changes affecting the legal rights and obligations of providers take effect. 42 U.S.C. § 1395hh(a)(2).

Count II: The Final Rule Should Be Set Aside as Arbitrary and Capricious

- 84. The plaintiff hospitals repeat the allegations in paragraphs 1–69 of this Complaint as if fully set forth herein.
- 85. In addition to being inconsistent with law and exceeding the agency's statutory authority, the final action is both arbitrary and capricious as well as unreasonable. First, the agency has still not acknowledged that the policy readopted in the 2023 rule from the vacated 2004 rule

previously readopted prospectively in 2013 during the *Allina* litigation departed from the preexisting rule and practice regarding the treatment of Part C days in the DSH payment and has not offered any good reason for that change. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089–90 (D.C. Cir. 2009) (observing that an agency must "acknowledge and provide an adequate explanation for its departure from established precedent").

- 86. CMS claims that "[t]his final action establish[es] a policy." 88 Fed. Reg. at 37,772; see id. at 37,774 ("[I]t is necessary for CMS to engage in retroactive rulemaking to establish a policy[.]"); id. at 37,776 ("[T]he decision in Allina II would require notice-and-comment rulemaking to establish the gap-filling policy stated in this action."); id. at 37,783 ("If rulemaking was required to change the Secretary's approach, as held in Allina II, then rulemaking was also required to establish the Secretary's approach in the first place."). As found by the Court of Appeals and this Court, history proves otherwise. See, e.g., Northeast Hosp., 657 F.3d at 16 ("confirm[ing] that [the Secretary] changed her interpretation of the DSH provision in 2004"); Allina I, 904 F. Supp. 2d at 79 ("After implementation of [Part C], 'between 1999 and 2004, the Secretary routinely excluded M+C [inpatient hospital] days from the Medicare [SSI] fraction." (citation omitted)). Before 2004, CMS excluded Part C days from Part-A-entitled days because Part C days are not covered or paid under Part A. See Allina II, 863 F.3d at 939 ("Before 2004, [Defendant's agency] had not treated Part C enrollees as 'entitled to benefits under Part A." (quoting Northeast Hosp., 657 F.3d at 15)); Allina I, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as not entitled to benefits under Part A.").
- 87. Since 2004, the agency has tried to change that position, but courts have blocked each of its unlawful attempts to do so for cost years before 2013. These court failures mean that,

following the vacatur of the 2004 rule, CMS has never effectively or lawfully departed from its pre-2004 policy for cost years prior to 2013. When a rule is vacated, that vacatur has the effect of reinstating the prior regulation. *See, e.g., United Steel*, 925 F.3d at 1287 (concluding that the effect of vacatur was to "automatically resurrect[]" the prior standard because the new rule "modifie[d]" a pre-existing standard); *Virgin Islands Tel. Corp. v. FCC*, 444 F.3d 666, 672 (D.C. Cir. 2006) (Vacatur "restored the *status quo ante.*"); *Croplife Am.*, 329 F.3d at 879 (vacating rule and holding that "[a]s a consequence, the agency's previous *practice* . . . is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation" (emphasis added)); *Action on Smoking & Health*, 713 F.2d at 797 ("[B]y vacating or rescinding the re[s]cissions . . . the judgment of this court had the effect of reinstating the rules previously in force" (citations omitted)); *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) (explaining that vacating a rule "[r]einstated" the prior rule "until the agency repromulgated the same rule").

A-entitled. See Allina II, 863 F.3d at 939 ("Before 2004, [Defendant's agency] had not treated Part C enrollees as 'entitled to benefits under Part A." (citation omitted)); Allina I, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as not entitled to benefits under Part A."); Northeast Hosp., 657 F.3d at 16 ("confirm[ing] that [the Secretary] changed her interpretation of the DSH provision in 2004"). The pre-2004 regulation, which was restored by the Court's vacatur in Allina I, dictates the exclusion of Part C days from the number of Part-A-entitled days in the Medicare DSH calculation. That pre-2004 regulation specifies that the Medicare Part A/SSI fraction includes only "covered" patient days, see 42 C.F.R. §§ 412.106(b)(2)(i) (2003), meaning days paid under Part A. Id. § 409.3; see also Catholic Health Initiatives, 718 F.3d at 921 n.5. Part C days are not covered by Part A because payment by private

Part C Medicare Advantage plans for services furnished to their Part C patients is *not* payment by Part A. *See* 42 U.S.C. § 1395w-21(a)(1); *Northeast Hosp.*, 657 F.3d at 6. Because this rule codifies a policy of counting Part C days for years prior to 2013 (the opposite of the pre-2004 policy), the agency has "depart[ed] from [its] prior policy *sub-silentio*," that is, without "display[ing] awareness that it *is* changing position." *Fox*, 556 U.S. at 515. The rule is, therefore, arbitrary and capricious.

- 89. The agency's about-face for periods before October 1, 2004, is also arbitrary and capricious because the agency has failed to explain its departure from its prior practice of acquiescing in the *Northeast Hospital* decision and settling hundreds and hundreds of cases by instructing its contractors to include Part C days in the numerator of the Medicaid fraction. This disparate treatment is particularly unfair to the plaintiff hospitals, at least one of which has not even had a chance to initiate appeals because the overdue NPRs have been delayed for a significant period of time. The lack of explanation for this differential treatment renders the 2023 rule arbitrary and capricious. *See Transactive Corp. v. United States*, 91 F.3d 232, 239 (D.C. Cir. 1996) (finding agency action arbitrary when it treats seemingly similar situations differently without explanation of the factual differences justifying dissimilar treatment).
- 90. The final rule is also arbitrary and capricious because the agency changed its pre2004 position without properly considering reliance interests. When an agency is "not writing on
 a blank slate," rational decision-making requires an agency "to assess whether there were reliance
 interests, determine whether they were significant, and weigh any such interests against competing
 policy concerns." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020)
 (citations omitted); *Mirror Lake Vill., LLC v. Wolf*, 971 F.3d 373, 376 (D.C. Cir. 2020) (explaining
 that agency action is arbitrary and capricious if it is "not 'reasonably explained'" (citation omitted)).

CMS violated this legal duty. It failed adequately to consider and to weigh financial reliance interests against the considerations that animated its policy. It dedicated a mere three sentences of its 2023 rule to financial reliance interests—one stating that no hospitals commented that they made financial decisions in reliance on the prior policy, another saying that reliance would be unreasonable, and a final one repeating the fiction that the rule does not reflect a change in agency policy. 88 Fed. Reg. at 37,785–88. But there were, in fact, numerous comments, including from Montefiore, stating that "DSH hospitals across the country relied on the agency making DSH payments in accordance with [prior policy]." Christopher Panczner, System Senior Vice President & Chief Legal Officer at Montefiore Medical Center, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Percentage" Disproportionate Patient (CMS-1739-P) at (Oct. 2, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0050; Michael Breslin, Group Senior Vice President & Chief Financial Officer & Treasurer, NewYork-Presbyterian, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at 4 (Oct. 2, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0058 ("The proposed rule ignores that DSH hospitals relied on the agency making DSH payments in accordance with the Court of Appeals' and Supreme Courts' decisions."); see also Brian Vamstad, Manager of Regulatory Affairs and Payment Policy at Allina Health, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at (Oct. 5, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0053; John Mallia, Executive Vice President and Finance/CFO of Maimonides Medical Center, Comments on Proposed Rule

"Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at 4 (Oct. 5, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0091 (same); Robert Nesselbush, EVP and Chief Financial Officer of Kaleida Health, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at 4 (Sept. 29, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0013 (same); Karen Kim, Vice President - Appeal Services of Toyon Associates, Inc., Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate (CMS-1739-P) Patient Percentage" 2, at 4 (Oct. 2020), https://www.regulations.gov/comment/CMS-2020-0089-0040 (same); Michael Newell, President of Southwest Consulting Associates, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at 7 (Oct. 1, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0025 (similar); Stephanie Webster, Partner at Ropes & Gray LLP, Comments on Proposed Rule "Medicare Program; Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage" (CMS-1739-P) at 14 (Oct. 5, 2020), https://www.regulations.gov/comment/CMS-2020-0089-0092 (similar).

91. The plaintiff hospitals, along with the other hospitals in the *Allina* litigation, raised similar arguments in their January 2015 comments in response to the Administrator's notification of review on remand, asserting that they relied on the unamended pre-2004 regulation and continuation of the agency's pre-existing policy. *See* Providers' Comments to CMS Adm'r on Remand, *Allina Health Servs. v. Blue Cross Blue Shield Ass'n*, PRRB Case Nos. 10-0165G et al.

at 39 (Jan. 23, 2015). More specifically, those comments explained that they reasonably forecasted their DSH funding based on the continuation of the pre-2004 standard and had no reason to project a reduction in such funding because CMS did not (1) actually adopt its change to the regulation in 2004 despite announcing its intent to adopt an abrupt policy reversal on Part C days; (2) issue SSI fractions treating Part C days as Part A days for FFYs 2005 and 2006; and (3) provide hospitals with accurate information concerning how that policy change would affect DSH payments once implemented. *See id.* at 37–43.

92. In any event, even if there were no such comments, CMS would still need to consider these financial reliance interests. See Regents of the Univ. of Cal., 591 U.S. at 8 (striking down rescission of government program for failure to consider reliance interests, even where the recission process did not involve an opportunity for notice and comment). CMS also entirely failed to mention non-financial reliance interests in its 2023 rule. Because reliance interests in the pre-2004 policy are "legally cognizable," the agency had a duty to consider these reliance interests even if, in the agency's view, its prior pre-2004 policy did not reflect the best reading of the statute. See id. at 1913–14 (holding that DHS needed to consider reliance interests even in a program it was rescinding because, in DHS's view, it lacked a legal basis). "[W]here the agency has failed to provide even [a] minimal level of analysis [regarding reliance interests], its action is arbitrary and capricious and . . . cannot carry the force of law." Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 217 (2016). Instead, an agency must provide a "reasoned explication for a regulation that is inconsistent with the Department's longstanding earlier position." *Id.* at 224. The agency's failure to respond adequately to such comments raising reliance interests, among other issues, is also arbitrary and capricious. See Cape Cod Hosp. v. Sebelius, 630 F.3d 203, 211-12 (D.C. Cir. 2011) ("The requirement that agency action not be arbitrary or capricious includes a requirement

that the agency . . . respond to relevant and significant comments." (internal quotation marks omitted)); *Reytblatt v. U.S. Nuclear Regul. Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997) (explaining that agencies "must respond in a reasoned manner to [comments] that raise significant problems"); *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking."), *vacated and remanded on other grounds sub nom. Becerra v. Gresham*, 142 S. Ct. 1665 (2022).

93. The agency has still failed to acknowledge and justify the enormous adverse financial impact on hospitals of the Part C days policy in the final action. CMS does not, and cannot, reconcile its assessment of the financial impact here as between "\$0" and "\$0.6 billion," 88 Fed. Reg. at 37,793, when it previously represented to the Supreme Court in seeking certiorari in Allina II that the impact with respect to the SSI fraction "alone implicates between \$3 and \$4 billion in reimbursement for FY2005 through FY2013," Pet. for Writ of Cert. at 14, Allina II, 587 U.S. 566 (2019) (No. 17-1484); see Allina II, 587 U.S. at 571 (observing that the inclusion of Part C days in the Medicare fraction "makes the fraction smaller and reduces hospitals' payments considerably—by between \$3 and \$4 billion over a 9-year period, according to the government"). Nor has the agency adequately explained why the policy change is appropriate despite the adverse impact on the nation's safety-net hospitals, like the plaintiff hospitals, that shoulder the financial burden of treating a disproportionate share of low-income patients. The agency also asserts that "[i]t is not clear what to compare an estimate of DSH payments under [the] final policy." 88 Fed. Reg. at 37,793. But by now, nearly 20 years after the agency first adopted the vacated policy that it seeks to readopt retroactively in this 2023 rule and over ten years after that policy was first vacated in Allina I and then readopted prospectively in 2013 during that litigation, CMS has had

more than enough time to do what is necessary with data at its disposal to calculate the effect of the Part C days issue accurately, particularly since the agency has been on notice since the 2012 district court decision in Allina I that its policy was invalid and the pre-2004 policy reinstated. If DSH payments made under the proposed rule would not differ from historical DSH payments, that is purely because CMS has erroneously continued to make payments to hospitals under its unlawful policy even after that policy was vacated twice. And given that "Medicare DSH payments have already been made under the policy reflected in the proposal," id. at 37,790, the agency should have been able to determine accurately the financial impact of the 2023 rule on hospitals. The rule is, therefore, arbitrary and capricious. See Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins., 463 U.S. 29, 43 (1983) (agency action is arbitrary and capricious where agency has "entirely failed to consider an important aspect of the problem"); Bus. Roundtable v. SEC, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011) (vacating a Securities and Exchange Commission rule as arbitrary and capricious because the agency had failed "adequately to assess the economic effects of a new rule" by, among other things, "inconsistently and opportunistically fram[ing] the costs and benefits of the rule" and "fail[ing] adequately to quantify the certain costs or to explain why those costs could not be quantified").

94. The agency's policy treating Part C days as Part A days is also contrary to the intent of Congress in enacting the DSH statute. *See Loper Bright*, 144 S. Ct. at 2268 (observing that courts interpret statutes "based on the traditional tools of statutory construction," not an agency's "individual policy preferences"); *see also Abramski v. United States*, 573 U.S. 169, 179 (2014) (stating that courts must interpret the relevant words of a statute "not in a vacuum, but with reference to the statutory context, structure, history and *purpose*") (internal quotations omitted) (emphasis added). The agency's interpretation conflicts with the purpose of the DSH adjustment,

which is to provide *additional* payments under the Part A prospective payment system for hospitals that incur higher costs in treating low-income patients who receive their benefits and coverage under Part A. *See* H.R. Rep. No. 99-241(I), at 15 *reprinted in* 1986 U.S.C.C.A.N. 579, 593–94. The policy reflected in the 2023 rule thus conflicts with the DSH statute and must be set aside as contrary to law. *See Loper Bright*, 144 S. Ct. at 2261 ("[C]ourts, not agencies, will decide '*all* relevant questions of law' arising on review of agency action . . . and set aside any such action inconsistent with the law as they interpret it.") (citations omitted).

- 95. In addition, the final rule also violates the requirements of the Regulatory Flexibility Act ("RFA"), which requires agencies to assess the negative impact of their rules on small businesses, including hospitals, *see* 5 U.S.C. §§ 604, 605(a)-(b). The agency claims in the rule that "the DSH payments . . . will not differ from historical payments for years after [F]FY 2005 for most hospitals," 88 Fed. Reg. at 37,790–92, and fails to conduct adequately a regulatory flexibility analysis, *see U.S. Telecom Ass'n v. FCC*, 400 F.3d 29 (D.C. Cir. 2005) (holding that the FCC violated the RFA by issuing a rule without a regulatory flexibility analysis and staying enforcement of the rule against small entities pending further regulatory analysis on remand).
- 96. The final action is also arbitrary and capricious for failing to consider and address *Empire Health* in the proposed rule while relying on it heavily in the final rule. The agency did not even mention *Empire Health* in its proposed rule, *see* 85 Fed. Reg. 47,723, despite the Ninth Circuit having ruled against the agency in May 2020, *see Empire Health*, 958 F.3d at 878. The agency's pattern is clear: it omitted *Empire Health* from the proposed rule when it was losing that case, and then introduced the case as a central rationale for its 2023 rule once it won the case. By ignoring this purportedly crucial case in its proposed rule, CMS engaged in arbitrary and capricious agency action. *See Util. Solid Waste Activities Grp. v. EPA*, 901 F.3d 414, 430 (D.C. Cir. 2018)

("An agency's failure to consider an important aspect of the problem is one of the hallmarks of arbitrary and capricious reasoning.").

- 97. The agency's continued application of the 2004 policy is also arbitrary and capricious because the agency has failed to provide a rational explanation for its inconsistent interpretation of the same phrase "entitled to benefits" within a single sentence of the DSH statute. See Transactive Corp., 91 F.3d at 237 ("A long line of precedent has established that an agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently."). With respect to the Part C days at issue here, the agency interprets "entitled to benefits" under Part A of Medicare to include all Medicare beneficiaries who have ever once met Medicare Part A eligibility requirements, regardless of whether they are entitled to payment of Part A benefits, while at the same time the agency construes that same phrase concerning SSI benefits to include only those days for patients who were entitled to have SSI benefits paid to them on those days. See 78 Fed. Reg. at 50,617; see also Baystate Med. Ctr. v. Leavitt, 545 F. Supp. 2d 20, 26 n.12, 42 (D.D.C. 2008).
- 98. Finally, the final rule is arbitrary and capricious because it is downright irrational and internally inconsistent. For example, on one hand, the agency claims that "if there is a gap in the statute to fill, the Secretary would be unable to calculate and confirm proper DSH payments for time periods before [F]FY 2014, which would be contrary to the public interest of providing additional payments to hospitals that serve a significantly disproportionate number of low-income patients, as expressed in the DSH provisions of the Medicare statute." 88 Fed. Reg. at 37,775. But on the other hand, the agency states (incorrectly) that "Medicare DSH payments have already been made under the policy reflected in the proposal." *Id.* at 37,790. The rule cannot be required

to fill a statutory gap "to avoid the consequences of legal ambiguity," *id.*, regarding payments if the agency has, in fact, already made those payments.

REQUEST FOR RELIEF

- 99. The plaintiff hospitals request an Order:
- a. declaring invalid and setting aside the agency's final action published in the *Federal Register* on June 9, 2023 (88 Fed. Reg. 37,772);
- b. declaring invalid and setting aside the final payment determinations reflecting the policy of including Part C days in the Medicare Part A/SSI fraction and excluding Medicaid-eligible Part C patient days from the numerator of the Medicaid fraction used to calculate the plaintiff hospitals' Medicare DSH calculation for the cost reporting periods at issue;
- c. declaring invalid and setting aside the Medicare Part A/SSI fractions issued by the agency and applied in the final payment determinations at issue here;
- d. directing the agency to recalculate the plaintiff hospitals' DSH payments by applying the pre-2004 policy and practice excluding Part C days from the SSI fraction and including Medicaid-eligible Part C patient days in the numerator of the Medicaid fraction and to make prompt payment of any additional amounts due to the plaintiff hospitals, plus interest calculated in accordance with 42 U.S.C. § 139500(f)(2);
- e. requiring the agency to pay legal fees and cost of suit incurred by the plaintiff hospitals; and
 - f. providing such other relief as the Court may consider appropriate.

Respectfully submitted,

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